## THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,	)
Plaintiff,	) ) ) C.A. No. 97-550 (SLR)
v.	)
MEDTRONIC VASCULAR, INC., et al.,	)
Defendants.	)
MEDTRONIC VASCULAR, INC.,	
Plaintiff,	) ) CAN-07-700 (SLD)
v.	) C.A. No. 97-700 (SLR)
CORDIS CORPORATION, et al.,	)
Defendants.	)

## MEDTRONIC VASCULAR INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER OF LAW ON CORDIS CORPORATION'S PATENT INFRINGEMENT CLAIMS

MORRIS, NICHOLS, ARSHT & TUNNELL

Karen Jacobs Louden (#2881) Leslie A. Polizoti (#4299) 1201 N. Market Street

P.O. Box 1347

Wilmington, DE 19899-1347

(302) 658-9200

Attorneys for Medtronic Vascular, Inc.

OF COUNSEL: Raphael V. Lupo Donna M. Tanguay Mark G. Davis D. Michael Underhill Michael W. Connelly McDERMOTT WILL & EMERY LLP 600 13th St., NW Washington, DC 20005-3096 (202) 756-8000

April 19, 2005

i.

# TABLE OF CONTENTS

		<u>Page</u>
NATURE AND STA	GE OF PROCEEDINGS	1
SUMMARY OF ARC	GUMENT	1
STATEMENT OF FA	ACTS	2
A.	The Asserted Claims of the '762 And '984 Patents All Recite The "Substantially Uniform Thickness" Limitation	2
В.	During The '762 Reexamination, Cordis Distinguished Prior Art That Had 100% Variations in Thickness, Which Cordis Said Was Not Of "Substantially Uniform Thickness	2
C.	The AVE Stents Have Non-Uniform, Tapered, Crowns	4
ARGUMENT		6
A.	The Substantially Uniform Thickness" Limitation Cannot Encompass A Stent With A Wall That Varies By as Much as 100 Percent	7
В.	The Walls Of The AVE Stents Vary By As Much As 100 Percent, And Therefore Cannot Infringe	9
C.	Cordis's Non-Infringement Theories Are Based Upon A Misreading Of The "Substantially Uniform Thickness" Limitation	10
CONCLUSION		18

## TABLE OF CITATIONS

	Page(s)
Cases	
Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352 (Fed. Cir. 2003)	passim
Elkay Mfg. Co. v. Ebco Mfg. Co. 192 F.3d 973 (Fed. Cir. 1999)	4, 17
Inverness Medical Switzerland GmbH v. Warner Lambert Co., 309 F.3d 1373(Fed Cir. 2002)	4
Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985 (Fed. Cir. 1999)	10
Litton Systems, Inc. v. Honeywell, Inc., 140 F.3d 1449 (Fed. Cir 1998)	7
Mycogen Plant Science, Inc. v. Monsanto Co., 61 F.Supp. 2d 199 (D. Del. 1999)	6
Pannu v. Iolab Corp., 155 F.3d 1344 (Fed. Cir. 1998)	6
Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888 (Fed. Cir. 1984)	7
Union Carbide Chemicals & Plastics Tech. Corp. v. Shell Oil Co., 163 F.Supp.2d 426 (D. Del. 2001)	10
Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996)	7
Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377 (Fed. Cir. 1999)	7
Other Statutes	
Fed.R.Civ.P. 50	1, 6

Following a trial in 2000, the Federal Circuit in 2003 remanded the case back to this Court. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1365 (Fed. Cir. 2003. On March 14, 2005, after a one-week retrial, a jury found the asserted claims of the '762 and '984 patents non-obvious and infringed by the MicroStent II, GFX and GFX II stents. (D.I. 1358.) Pursuant to the verdict, this Court on March 31, 2005, entered judgment in favor of Cordis Corporation ("Cordis") and against Medtronic Vascular, Inc. ("AVE"). (D.I. 1374.)

AVE moved for judgment as a matter of law ("JMOL") at the close of Cordis's infringement case and at the close of evidence and pursuant to Fed. R. Civ. P. 50(a). (See Docket Entry of 3/11/05 and D.I. 1389, 3/9/05 Tr. 970:23-971:10; D.I. 1391, 3/11/05 Tr. 1742:12-1743:16). AVE timely renewed its motion for JMOL pursuant to Fed. R. Civ. P. 50(b) on April 14, 2004. (D.I. 1384). Pursuant to the stipulation by the parties and as ordered by this Court (D.I. 1378), AVE files this opening brief in support of its renewed motion for JMOL.

### SUMMARY OF ARGUMENT

No reasonable jury could have found that AVE infringed the asserted claims of the '762 and '984 patents. The jury was asked to decide whether the accused products have tubular members with walls having a "substantially uniform thickness." In contrast, the leading and trailing edges of the ring-portions of the walls of the AVE stents are tapered. The maximum thickness of the walls of each AVE stent in the area of the struts is more than twice as thick as the wall thickness at the tapered portions of the crowns. The evidence at trial was undisputed on these points. As a result, the walls in

Page 5 of 22

the AVE stents vary in thickness by as much as 100 percent, and thus by definition do not meet the "substantially uniform thickness" limitation. Thus, judgment as a matter of law of non-infringement should be granted.

#### STATEMENT OF FACTS

A. The Asserted Claims of the '762 And '984 Patents All Recite The "Substantially Uniform Thickness" Limitation

Cordis asserted two patents at trial: the '762 patent and the '984 patent. The '762 patent is directed to a slotted tube stent. (PX-3.) The '984 patent is directed to flexibly connecting the prior art slotted tube stents with a single connector member, parallel to the longitudinal axis. (PX-6.) The preferred embodiments in both patents each have a wall with a "uniform thickness." (PX-3 at 6:41-44 & 7:30-33; PX-6 at 5:64-67, 6:51-54 & 10:36-41.) Therefore, the thickness of the walls along the length of each preferred stent embodiment does not vary.

The asserted claims all require a tubular member, or plurality of tubular members, with a wall having a "substantially uniform thickness." (PX-3 and PX-4, claims 23, 51 and 54; PX-6, claims 1 and 3.)

> B. During The **'**762 Reexamination, Distinguished Prior Art That Had 100% Variations in Thickness, Which Cordis Said Was Not Of "Substantially Uniform Thickness

During the reexamination of the '762 patent, Cordis and its consultant, Dr. Andros, represented that if some portions of the wall of an implant are twice as thick as other areas, then the wall thickness is not "substantially uniform." They made these

Page 6 of 22

statements to distinguish the slotted tube sleeve disclosed in the Ersek patent. (PX-95.) For example, in his declaration, Dr. Andros states:

> The Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is twice as thick in some areas as in others, and the thickness of the wall varies throughout.

(PX-13 at PWRAP 003079 SUB.<sup>1</sup>)

In an amendment accompanying the Andros declaration, Cordis explained that the reason for this variation is that the bonds and bridge areas of Ersek protrude outwardly:

> [I]n the first diameter configuration [of the Ersek sleeve], the wall of sleeve 16 is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material. Moreover, the bonds or bridges at the junctions of the strands protrude inwardly and outwardly of the plane of the starting material, and as a result the Ersek sleeve 16 has a non-uniform wall of varying thickness.

(*Id.* at PWRAP 003055 SUB.)

While Dr. Andros characterized this variation as leading to an "expanded metal sleeve [that] is twice as thick in some areas as in others," (PX-13 at PWRAP 003079 SUB), Cordis characterized the change as a "100% variance" (id. at PWRAP 003049 SUB; see, also PX-13 at PWRAP 003009, 0030050, and 0030100 SUB).

The file history also makes clear that, even if the non-uniformity in wall thickness is confined to a small area at the end of a device, the device falls outside the scope of the patent claims. After the examiner cited the Lazarus prior art in the '762 application, Cordis pointed out that the Lazarus device had hooks that extended

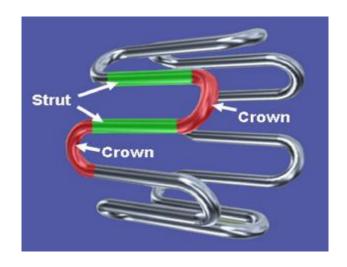
<sup>&</sup>lt;sup>1</sup> Emphasis in the quoted material is added unless otherwise noted.

outwardly at one end of the device. In his "reasons for allowance," the examiner noted that the presence of even this limited area of non-uniformity in wall thickness at one end of the device took the Lazarus patent outside the scope of the '762 patent's claims. (PX14, Tab 58 at PWRAP 3259.)

Because Cordis did not object to that reason for allowance, it limited the scope of the claims. Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973 (Fed. Cir. 1999); Inverness Medical Switzerland GmbH v. Warner Lambert Co., 309 F.3d 1373, 1380 (Fed Cir. 2002) ("failure to object to an examiner's interpretation of a claim ordinarily disclaims a broader interpretation").

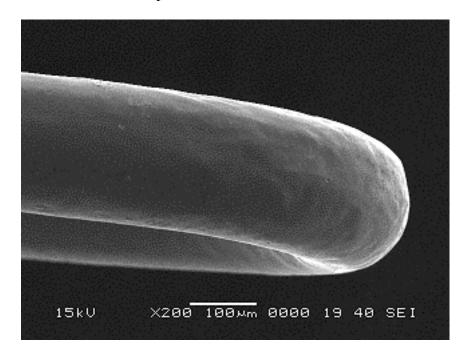
#### The AVE Stents Have Non-Uniform, Tapered, C. Crowns

The AVE stents accused of infringing these patents are the MicroStent II, the GFX, and the GFX2. (D.I. 1358.) These stents consist of a series of rings that have been laser fused together. (D.I. 1389, 3/9/05 Tr. at 1009:1-1012:6.) As shown on the figure below, each of the rings is of "a sinusoidal design characterized by a series of peaks and valleys called 'crowns' interconnected by substantially straight portions called 'struts.'" (D.I. 1128 at 19; see also D.I. 1389, 3/9/05 Tr. at 1002:20-1003:2, 1006:2-8).



Filed 04/19/2005

The thickness of the material along the length of each ring varies. (D.I. 1389, 3/9/2005 Tr. at 1109:21-1111:11, 1120:1-9.) The thickness of the wall in the area of the struts is more than double the thickness of the wall at the area near the ends of the crowns. (Id.) This variation in thickness can be illustrated with a scanning electron micrograph of a Microstent II, which is reproduced below:



(DX-10167A.)

As seen above in a closeup of a single crown, the MicroStent II has a tubular form comprised of individual rings that taper on each leading and trailing edge. Although they have a slightly different geometry, this same feature is present in the GFX and GFX II. (DX 10166A; DX 10167A; D.I. 1389, 3/9/205 Tr.at 1027:6-1029:14 & 1030:16–1033:9). Hence, the thickness of the wall increases by more than one hundred percent (i.e., the thickness more than doubles) as one moves from one end toward the greater thickness along the struts, and decreases by the same amount as one approaches the other end of the ring element. (D.I. 1389, 3/9/05 Tr. at 1110:2-1111:5.)

The Federal Circuit explained that this variable thickness is illustrated by using a series of imaginary circles along the length of the ring element. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1362 (Fed. Cir. 2003). See also D.I. 1389, 3/9/05 Tr. at 1101:13-1102:20. If a series of imaginary circles is placed along both the inner and outer surfaces of the imaginary wall of each ring of the accused stents, the distance between the intersections of each of the respective circles and the inner and outer surfaces of the wall will vary. (D.I. 1389, 3/9/05 Tr. at 1110:2-1111:11 & 1119:6-1120:5.) It was not disputed at trial that the distance between respective circles in the center of the sinusoidal ring element would be more than twice as much as the distance between respective circles as one nears either end of the sinusoidal element. (D.I. 1389, 3/9/05 Tr. at 1110:18-1111:5 & 1122:6-15.)

#### <u>ARGUMENT</u>

Renewed motions for JMOL are governed by Federal Rule of Civil Procedure 50(b), and are appropriate in patent cases as in any other. See, e.g., Mycogen Plant Science, Inc. v. Monsanto Co., 61 F. Supp. 2d 199, 236-37 (D. Del. 1999) (granting in part and denying in part plaintiff's post trial motions for JMOL on infringement and validity). To prevail on a renewed motion for JMOL following a jury trial, a party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)).

The issue raised by AVE's renewed motion is whether Cordis proved literal infringement. Determining whether an accused product infringes the claims of a patent is a two-step process. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed. Cir. 1996). First, the meaning of the claim terms must be construed, as a matter of law, and second the claims as construed must be compared to the accused product or process, which is a question of fact. Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1380-81 (Fed. Cir. 1999). Moreover, "literal infringement requires that the accused device contains each limitation of the claim exactly; any deviation from the claim precludes a finding of literal infringement." Litton Sys., Inc. v. Honeywell, Inc. 140 F.3d 1449, 1454 (Fed. Cir 1998).

> The Substantially Uniform Thickness" Limitation A. Cannot Encompass A Stent With A Wall That Varies By as Much as 100 Percent

The sole infringement issue at trial was whether the AVE stents literally meet the "substantially uniform thickness" limitation. (D.I. 1357 at 16.) The Court instructed the jury that "substantially uniform thickness" means:

> The wall of a tubular member must be of largely or approximately uniform thickness. A wall that varies in thickness by as much as 100 percent cannot be said to be of substantially uniform thickness.

(D.I. 1357 at 22-23.) The second sentence of the instruction frames the crucial non-infringement issue: whether the AVE stents have walls that vary by as much as 100 percent. Before this issue can be determined, however, the construction of three

additional phrases must be ascertained: (1) "wall;" (2) "thickness;" and (3) "100 percent" variance.

The Federal Circuit provided the answers. With respect to the "wall" of the tubular member, the Federal Circuit found that the wall is identified by drawing imaginary circles intersecting with the outermost points along the length of the tubular member:

> The district court described the wall surface by stating "the outer surface of the tubular member must be disposed in a common cylindrical plane." That common "cylindrical plane" is formed by an *imaginary circle* that intersects with the outermost point of *each* round strut.

Cordis, 339 F.3d at 1362.

The "thickness" at any point along the wall is the distance between the circle and a corresponding circle on the inside of the stent:

> The thickness of the wall is equal to the diameter of each round strut, i.e., the distance between the outer point that intersects the wall surface and the corresponding inner point that intersects a similar imaginary cylindrical surface on the inside of the tubular member.

#### *Id.* This claim construction controls here.

Finally, a wall varying by as much as "100 percent" is simply a wall that is twice as thick in some areas as in others (i.e., has a double thickness). The Federal Circuit held that "a wall that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either literally or by equivalents." Id. Indeed, in reaching this conclusion, the Federal Circuit interchangeably referred to the wall's "double thickness" and "100 percent" variance. *Id.* at 1361-62. For example, it quoted the following remarks made by Dr. Andros during the '762 reexamination in support of its opinion:

[T]he Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is *twice as thick in some areas as in others*, and the thickness of the wall varies throughout.

*Id.* at 1362 (quoting PX-13 at PWRAP 003079 SUB). Hence, it is clear that a wall having a "100 percent" variance is the same as a wall that is twice as thick in some areas as in others. *Id.* at 1361-62.

# B. The Walls Of The AVE Stents Vary By As Much As 100 Percent, And Therefore Cannot Infringe

The structure of the AVE stents is not in dispute.

AVE's stents each have a tapered crown with variable thickness. Cordis concedes this point, noting in its closing argument that "there is a variation [] at the end" of the AVE stents. (D.I. 1391, 3/11/05 Tr. at 1766:20-21.) This variation is "substantial." For each AVE stent, the maximum thickness of the wall in the area of struts is more than twice as thick as the wall thickness near the end of the crowns. (D.I. 1389, 3/9/2005 Tr. at 1109:21-1111:11 & 1120:1-9.) In other words, the walls vary by more than 100 percent because the AVE stents are "twice as thick in some areas as in others." Cordis, 339 F.3d at 1362 (quoting PX-13 at PWRAP 003079 SUB). Again, Cordis's experts did not dispute this fact. Indeed, they never even measured a single AVE stent. (D.I. 1387, 3/7/05 Tr. at 556:15-18; D.I. 1388, 3/8/05 Tr. at 912:22-913:22.)

Because "[a] wall that varies in thickness by as much as 100 percent cannot be said to be of substantially uniform thickness," the AVE stents cannot as a matter of law infringe the claims. (D.I. 1357 at 22-23.) Moreover, because Cordis never even measured the variation in thickness of the AVE stents and failed to provide any evidence of the thickness of their walls, it has not met its burden of proof that the AVE

stents have a "substantially uniform thickness." For either of these reasons, the Court should enter JMOL that the AVE stents do not infringe.

> C. Cordis's Non-Infringement Theories Are Based Upon A Misreading Of The "Substantially Uniform Thickness" Limitation

At trial, Cordis presented a number of misguided infringement arguments aimed at confusing the jury. None of the arguments, however, raise a factual dispute concerning the structure of the AVE stents. All involve issues of law -i.e., the interpretation of the patents. As a result, the Court can properly enter judgment of noninfringement. Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 163 F. Supp. 2d 426, 441 (D. Del. 2001) ("Because the record on this issue has been fully developed and the court finds no disputed issues of fact, the court will also enter judgment as a matter of law in favor of Union Carbide on this issue."). See also Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1999) ("Because the relevant aspects of the accused device's structure and operation are undisputed in this case, the question of whether [the accused] product infringes the claims . . . turns on the interpretation of those claims," which is an issue of law.)

> 1. Cordis Attempted to Eviscerate the 100% Variation Exclusion in the Court's Claim Construction

Cordis's primary attempt at misdirection was to argue to the jury that the AVE stents do not have a 100% variation in thickness because -- to have a variation of 100% -- the wall thickness would have to drop to zero at some point. Cordis alleged that such a deviation is allegedly mathematically impossible. Cordis disclosed this infringement theory for the first time in this 8-year litigation during Cordis's closing

Page 14 of 22

arguments. It is obvious why Cordis concocted this last-minute theory. As Cordis's counsel conceded during closing, the AVE stents have a variable thickness:

> Well, there is – I mean, there is a variation here at the end [of the AVE stents], just like there is a variation here and here and here and here and here, but it goes downward, it's a negative deviation. It doesn't go down a hundred percent. If it went down a hundred percent, there wouldn't be any stent... You can't have a hundred percent deviation.

(D.I. 1391, 3/11/05 Tr. at 1766:20-1767:10; see also discussion in AVE's New Trial Brief, filed herewith.)<sup>2</sup>

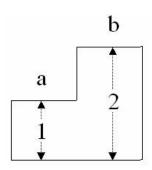
Cordis's theory is inconsistent with both the Federal Circuit decision and the prosecution history of Cordis's patents. By contending that "you can't have" a stent with a 100% variation in wall thickness, Cordis argues that the Federal Circuit's limitation on the scope of the claims is meaningless. As explained above, the Federal Circuit said that a wall having an area that is twice as thick in one area as opposed to others varies by as much as 100%. Cordis, 339 F.3d at 1361-62. Indeed, it quoted the following remarks made by Dr. Andros during the '762 reexamination in reaching its conclusion that variances in thickness of 100% are not covered by the claims:

> The Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is twice as thick in some areas as in others, and the thickness of the wall varies throughout.

*Id.* at 1362 (quoting PX-13 at PWRAP 003079 SUB).

Even under Cordis counsel's theory, AVE still would not infringe. According to Cordis, in order to have a negative deviation of 100%, the thickness has to go to zero, where there is not "any stent." However, at the end of the taper at the leading and trailing edges of the AVE stents, there is, in fact, not "any stent."

Taking the figure to the right as an example, it has double thickness (a "1" to "2" ratio of thickness at points "a" and "b"). Mathematically, then, its thickness varies by 100%:



Percentage variation = 
$$(b - a)/a$$
 times 100

Percentage variation = 
$$(2 - 1)/1 * 100 = (1)/(1) *$$

100 = 100%.

Similarly, if the thinner wall area were one-fourth the thickness of the thinner area, the percentage variation in thickness would be 300%; if it were one tenth the thickness, the percentage variation in thickness would be 900%:

Percentage variation = 
$$(2 - .5)/(.5) * 100 = (1.5)/(.5) * 100 = 300\%$$

Percentage variation = 
$$(2-.2)/(.2) * 100 = (1.8)/(.2) * 100 = 900\%$$

If one were to adopt Cordis's newly-minted interpretation of 100% variation, even the Ersek device, which was expressly described in the prosecution history as having a 100% variation in thickness, would not have a 100% variation in thickness because the thickness of the walls of the Ersek device never falls to zero.

In this regard, Cordis's own expert, Dr. Buller, agrees with AVE and the Federal Circuit, not Cordis's counsel. Dr. Buller testified that the distinguishing remarks in the '762 reexamination file history related to "areas [in the Ersek sleeve] that are twice as thick as other areas, so it's got a thickness that is twice as thick." (D.I. 1388, 3/8/05 Tr. at 758:8-18; *see also* Tr. 886:1-5.)

In short, far from being an impossibility, if the thickness along a stent is "twice as thick in some areas as in others," then there is a 100 percent variance. Because

it is undisputed that the walls of the AVE stents are twice as thick in some areas as in others, they cannot infringe.

> 2. Cordis Focused On The Cross-Section Of The AVE Starting Material Rather Than The Alleged "Walls" Of The Stent

Ignoring that the walls of the AVE stents are at least twice as thick in some areas as in others, Cordis improperly focused on the cross-section of the AVE starting material, not on the "wall" of the alleged tubular member in the AVE stents. According to Cordis, because the starting material of the AVE stents is a round toroid with a substantially uniform cross-section, and because the AVE stents have a uniform cross-section, the AVE stents allegedly meet the substantially uniform thickness limitation.<sup>3</sup> (D.I. 1386, 3/4/05 Tr. at 136:17-137:1 & 139:7-140:14; 3/7/05 Tr. 535:1-537:3; 3/11/05 Tr. at 1754:13-22 & 1757:7-1762:3).

Cordis is wrong. First, the starting material is irrelevant to the claims. Cordis, 339 F.3d at 1357 ("[W]e decline to superimpose a process limitation on the product claims at issue.") The relevant inquiry is whether the final product has a "substantially uniform thickness," not what the stents are made of.

Second, the "substantially uniform thickness" language is directed at the "wall" of the tubular member, not the cross-section of a strut. Indeed, the Federal Circuit

Cordis's relied on AVE's documents to demonstrate that the cross-section of the stents at the crowns and struts do not vary substantially. These documents do not contradict the fact that the wall thickness at the crown of the AVE stents varies (which Cordis concedes is correct). Indeed AVE's documents conclusively demonstrate both the tapered, variably thick crowns, and that the "circle within a

circle" methodology is appropriate to measure wall thickness. (D.I. 1389, 3/9/05 Tr. at 1060:13-1062:13; 1085:9-1087:15; 1090:5-1092:4; 1117:1-1124:1.)

3

Page 17 of 22

expressly held that it is wrong to focus solely on the round cross-section of struts, as it is possible that "a stent with round struts can have a substantially uniform thickness as long as the round struts have substantially the same diameter." Cordis, 339 F.3d at 1362.4 Instead, it held that the focus should be on the uniformity of the wall thickness along the length of the tubular member. See id. at 1360 ("Accordingly, the 'substantially uniform' limitation also requires that the thickness of the wall surface be sufficiently uniform along its *length* and between members to allow uniform expansion of the stent.").<sup>5</sup> This thickness is the distance between corresponding imaginary circles on the inside and outside of the tubular member. *Id.* at 1362.

Cordis's own expert, Dr. Andros - whom Cordis hired to argue to the PTO, inter alia, that the wall thickness of Ersek is not "substantially uniform" – agrees. He testified as follows:

> Q. Okay. I'm really not asking for a quantitative measurement. I'm saying – what I'm asking is: What are the two points between which you would measure the thickness?

> A. Well, if you were going to measure the thickness and this were a tube and you had a micrometer that could do that, you could you would test various points along the wall with a micrometer.

As described above, and as this Court has explained, AVE's stents have two components: struts and crowns (D.I. 1127 at 19 ("The rings are bent from their normal configuration into a sinusoidal design characterized by a series of peaks and valleys called 'crowns' interconnected by substantially straight portions called 'struts.'").) AVE's non-infringement argument focuses on substantial variations in thickness along the length of the stent, which implicates the tapered crowns and not the struts. The reason is that along the length of the stent, the thickness of the struts does not vary substantially. The thickness in the region of the crowns does vary substantially.

<sup>5</sup> The '762 patent focuses on the thickness of the stent's wall along its length when describing the "substantially uniform thickness" limitation. (PX-3, '762 patent at 7:26-41.)

Or if you're going to do it in another sense, you can draw a circle around the outside and a circle around the inside, and measure the difference between the two radii or the diameters. And if you were to slice that tube up and down the length of it or perpendicular to the long axis, you would then get uniform thickness from top to bottom.

(D.I. 1391, 3/11/05 Tr. at 1724:11-1725:3.)

When the actual "walls" of the AVE stents are measured in the manner the Federal Circuit described, the undisputed evidence established that there are variations in thickness of at least 100%.

Even assuming for the sake of argument that the "circle within a circle" methodology were not the only appropriate test, the Federal Circuit's decision clearly endorsed this methodology. Cordis failed to offer any evidence using this methodology or rebut AVE's evidence that, using the Federal Circuit methodology, the walls of the AVE stents have variations in thickness of at least 100%. AVE should be granted judgment as a matter of law.

#### 3. Cordis Ignored The Crowns Of The AVE Stents

Finally, Cordis's infringement analysis ignores the crowns of the AVE stents. Cordis argues that because the vast majority of the stent has a substantially uniform thickness, the variation in thickness near the ends of the crowns is irrelevant. (D.I. 1386, 3/4/05 Tr. at 140:5-141:16; D.I. 1391, 3/11/05 Tr. at 1764:23-1766:17).

Once again, Cordis's analysis is contrary to the Court's claim construction and to the '762 reexamination certificate. The Court instructed the jury that: "[a] wall that varies in thickness by as much as 100 percent cannot be said to be of substantially uniform thickness." (D.I. 1357 at 22-23.) If any portion of the wall varies by 100%, it

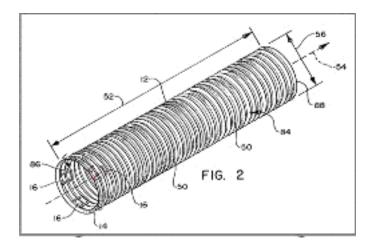
Page 19 of 22

falls within this exclusion. Here, there is no dispute that the variably thick crowns are part of the "wall" of the stent. Jeff Allen testified for AVE that the tapered ends provide support to the vessel wall upon deployment. (D.I. 1389, 3/9/05 Tr. at 1023:23-1024:17 and 1058:22-1059:12) Dr. Buller, Cordis's expert, concurs that the tapered portions of the crowns are part of the wall:

- Q. . . . [W]here is the wall, the wall that you look at to measure substantially uniform thickness? Does it run from end to end of the stent?
- A. All of the metal is the wall of the stent. The metal is the wall of the stent.
- Q. So would you agree with me that the wall runs from here to here, is that fair to say?
- A. Yeah.
- Q. Thank you. And again, I guess I ought to be a little more precise. With the curvature, would you agree with me that it runs from the outer most point of the crown there to the outer most point of the crown there, would that be fair?
- A. Well, the metal of the stent runs from there, that is true.
- Q. So the wall of the stent runs from the outer most point of the crown to the outer most point of the crown; correct?
- A. The wall of the stent does.
- Q. The wall of the stent does?
- A. The wall of the stent does, yes.

#### (D.I. 1388, 3/8/05 Tr. at 915:19-916:18)

Cordis's argument that a variation in thickness that extends over only a limited portion of the length of the wall can be ignored is also contrary to the prosecution history of the patents. During the '762 reexamination, Cordis distinguished the claims from a graft disclosed in a patent to Lazarus. (DX-4029.) The Lazarus graft, illustrated below, includes staples 16.



Even though the staples (shown in red above) span a tiny fraction of the length of the graft near one end, the Patent Office found that the thickness of the staples precluded the Lazarus graft from having a "substantially uniform thickness." (PX14, Tab 58 at PWRAP 3259.) This reason for allowance, to which Cordis did not object, informed the public that a substantial variation in wall thickness takes a device outside the scope of the Cordis patent claims even if that substantial variation extends over a limited portion of the length of the stent. *Elkay Mfg Co.*, *supra*.

In short, it is irrelevant whether or not the variation in thickness occurs over a small fraction of the length of the stent or only near the end of the stent. If some areas of the wall are twice as thick as others – that is, if the variation in wall thickness is 100% or more -- then the stent cannot infringe.

#### CONCLUSION

For the foregoing reasons, and for the reasons stated in AVE's Opening Brief in Support of a New Trial filed herewith, AVE respectfully requests that the Court grant its renewed motion for judgment as a matter of law on Cordis's patent infringement claims.

MORRIS, NICHOLS, ARSHT & TUNNELL

/s/Karen Jacobs Louden

Karen Jacobs Louden (#2881) Leslie A. Polizoti (#4299) 1201 North Market Street P.O. Box 1347 Wilmington, Delaware 19899 (302) 658- 9200

Attorneys for Medtronic Vascular, Inc.

Raphael V. Lupo Donna M. Tanguay Mark G. Davis D. Michael Underhill Michael W. Connelly McDERMOTT, WILL & EMERY 600 13th Street, NW Washington, DC 20005 (202) 756-8000

461279

## **CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on April 19, 2005 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

> Steven J. Balick **Ashby & Geddes** 222 Delaware Ave., 17th Flr. P.O. Box 1150 Wilmington, DE 19899

Josy W. Ingersoll Young, Conaway, Stargatt & Taylor LLP 1000 West Street, 17th Floor P.O. Box 391 Wilmington, DE 19899

MORRIS, NICHOLS, ARSHT & TUNNELL

/s/Karen Jacobs Louden

Karen Jacobs Louden (#2881) Leslie A. Polizoti (#4299) 1201 North Market Street P.O. Box 1347 Wilmington, Delaware 19899 (302) 658-9200 Attorneys for Medtronic Vascular, Inc.

klouden@mnat.com